OCT 3 1 2001

K011761

SECTION 2. 510(k) SUMMARY

P.O. Box 12888
Reading, PA 19612

ARROW INTERNATIONAL

Research/Engineering
2400 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 478-3188

Submitter: Arrow International
2400 Bernville Road
Reading, PA 19605

Contact person: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Phone: (610) 478-3137
Fax: (610) 478-3172
E-mail: tom.nickel@arrowintl.com

Date summary prepared:

Device trade name: MAC™Two-Lumen Central Venous Access Kit with ARROWg+ard Blue® and Hemostasis Valve/Side Port

Device common name: Two-Lumen Central Venous Access device

Device classification name: DBY, Class II at 21 CFR 870.1340, Introducer Catheter
FOZ, Class II at 21 CFR 880.5200, Intravascular Catheter

Legally marketed devices to which the device is substantially equivalent:

1. K993933: Arrow 14 Fr & 12 Fr Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Antimicrobial Catheter for High Volume Infusions
2. K002507: Arrow Two-Lumen Central Venous Access Kit with Hemostasis Valve/Side Port
3. K940079: Arrow SUPER ARROWFLEX™ Percutaneous Sheath Introducer Kit with ARROWg+ard Blue® and Arrow Raulerson Syringe

Description of device:

The proposed device is a modification to Arrow's Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve/Side Port, with the addition of ARROWg+ard Blue® antimicrobial surface treatment. The proposed device was created to help provide protection against device-related infections. It is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use.

The catheterization kit components are configured in a high-impact polystyrene (HIPS) tray, sealed with a Tyvek® lidstock, and sterilized.

Intended use of the device:

The MAC™ Two-Lumen Central Venous Access Device with ARROWg+ard Blue® permits venous access and catheter introduction to the central circulation. It may be inserted into the jugular, subclavian, or femoral veins. The ARROWg+ard® technology is intended to help provide protection against catheter-related infections. Clinical data have not been collected that demonstrate the use of the ARROWg+ard® antimicrobial surface in decreasing catheter-related infections for this device. It is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use..

Technological characteristics:

The proposed device has the same technological characteristics as the predicate devices.

Performance tests:

The following performance tests are included in the submission:

1. Tensile
2. Leak
3. Elongation
4. Flow Rate with Catheter
5. Flow Rate without Catheter
6. Priming Volume
7. Flex
8. Burst
9. *In vitro* efficacy – zone of inhibition
10. *In vitro* safety – elution profile
11. Hemolysis
12. Fatigue life testing
13. Stability tests
14. Biocompatibility tests

Conclusions:

The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs & Quality Assurance
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K011761
Trade/Device Name: MAC™ Two-Lumen Central Venous Access Kit with ARROWg+ard, Blue® Access Device and Integral Hemostasis Valve
Regulation Number: 870.1340 and 880.5200
Regulation Name: Introducer Catheter and Catheter, Intravascular short-term
Regulatory Class: II
Product Code: DYB and FOZ
Dated: September 17, 2001
Received: September 18, 2001

Dear Mr. Nickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS

510(k) Number (if known): K011761

Device Name: MAC™Two-Lumen Central Venous Access Kit with ARROWg+ard Blue® Antimicrobial Surface and Integral Hemostasis Valve/Side Port.

Indications for Use: The MAC™Two-Lumen Central Venous Access Device with ARROWg+ard Blue® permits venous access and catheter introduction to the central circulation. It may be inserted into the jugular, subclavian, or femoral veins. The ARROWg+ard® technology is intended to help provide protection against catheter-related infections. Clinical data have not been collected that demonstrate the use of the ARROWg+ard® antimicrobial surface in decreasing catheter-related infections for this device. It is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011761